MICHIGAN DEPARTMENT OF COMMUNITY HEALTH

CERTIFICATE OF NEED REVIEW STANDARDS FOR MEGAVOLTAGE RADIATION THERAPY SERVICES/UNITS

(By authority conferred on the Certificate of Need Commission by Section 22215 of Act No. 368 of the Public Acts of 1978, as amended, and sections 7 and 8 of Act No. 306 of the Public Acts of 1969, as amended, being sections 333.22215, 24.207, and 24.208 of the Michigan Compiled Laws.)

Section 1. Applicability

Sec. 1. (1) These standards are requirements for approval and delivery of services for all projects approved and certificates of need issued under Part 222 of the Code that involve megavoltage radiation therapy (MRT) services/units.

(2) A megavoltage radiation therapy service/unit is a covered clinical service for purposes of Part 222 of the Code. A megavoltage radiation therapy service/unit previously approved pursuant to Section 8 of these standards now seeking approval to operate pursuant to sections 5, 6, 7, 9, or 10 shall be considered as a person requesting certificate of need approval to begin or expand, as applicable, operation of an MRT service/unit. A megavoltage radiation therapy unit approved to operate as a special purpose MRT unit seeking approval to operate as a non-special MRT unit shall be considered as a person requesting certificate of need approval to begin or expand, as applicable, operation of a non-special MRT service/unit.

(3) The Department shall use sections 5, 6, 7, 9, and 10, as applicable, in applying Section 22225(1) of the Code, being Section 333.22225(1) of the Michigan Compiled Laws.

(4) The Department shall use Section 15, as applicable, in applying Section 22225(2)(c) of the Code, being Section 333.22225(2)(c) of the Michigan Compiled Laws.

(5)(a) These standards shall apply to the review of all CON applications for megavoltage radiation therapy services for which the Director of the Department of Community Health has not made a final decision under Section 22231(9) of the Code, being Section 333.22231(9) of the Michigan Compiled Laws, as of the effective date of these standards.

(b) In the case of an application that has been deemed submitted but that has not received a final decision by the Director on the effective date of these standards, the applicant may request and the Department shall grant, an extension of up to 60 days to the Director's decision date established under Section 22231(9) of the Code, being Section 333.22231(9) of the Michigan Compiled Laws. This period shall be used for the submission and review of any information which may be necessary to show compliance with these standards. The Department shall consider this information before a final decision is made.

(c) If a final decision reverses a proposed decision approving the project, the administrative hearing provisions of Section 22231(8) of the Code, being Section 333.22231(8) of the Michigan Compiled Laws, shall apply. If the proposed decision was a denial and an administrative hearing has been held, the Director shall permit a rehearing or continuation of the hearing in order to consider information submitted under this subsection and shall consider the results of that hearing before a final decision is made.

Section 2. Definitions

Sec. 2. (1) As used in these standards:

(a) "Acquisition of a MRT service/unit" means the acquisition (including purchase, lease, donation, or other comparable arrangement) of an MRT service/unit listed on the Department Inventory of MRT Units.

(b) "Begin operation of an MRT service/unit" means the establishment of a non-special MRT service/unit at a geographic location where an MRT service/unit is not currently provided that will result in an increase in the number of non-special MRT units listed on the Department Inventory of MRT Units. The relocation of an MRT unit, meeting the requirements of Section 10, to a geographic location within the same planning area shall not be considered as beginning operation of an MRT service/unit.

(c) "Brachytherapy" means the administration of radiation therapy by applying a radioactive material inside or in close proximity to the patient. The material may be contained in various types of apparatus~~,~~; may be on the surface of plaques; or may be enclosed in tubes, needles, wire, seeds, or other small containers. Common materials that are or have been used for the administration of brachytherapy include but are not limited to radium, Cobalt-60, Cesium-137, Iodine-125, and Iridium-192.

(d) "Cancer treatment program" means a coordinated, multi-disciplinary approach to the treatment of patients with cancer or other neoplasms, which must provide on-site simulation capability~~,~~ and, either on-site or through written agreements with other providers, all of the following services: (i) access to consultative services from all major disciplines needed to develop a comprehensive treatment plan, (ii) a computer-based treatment planning system, (iii) medical radiation physicist involvement, (iv) megavoltage radiation therapy capability including electron beam capability, (v) treatment aid fabrication capability, (vi) brachytherapy, (vii) a multi-disciplinary cancer committee, (viii) a tumor registry, (ix) patient care evaluation studies, and (x) cancer prevention and education programs.

(e) "Certificate of Need Commission" or "Commission" means the Commission created pursuant to Section 22211 of the Code, being Section 333.22211 of the Michigan Compiled Laws.

(f) “Code” means Act No. 368 of the Public Acts of 1978, as amended, being Section 333.1101 et seq. of the Michigan compiled Laws.

(g) "Complex treatment visit" means a treatment visit involving three or more treatment sites, tangential fields with wedges, rotational or arc techniques or other special arrangements, or custom blocking.

(h) "Computer based treatment planning system" means a computer system capable of displaying radiation doses and dose distributions within a patient using anatomical data from that patient and using measured radiation output data from the specific unit used to treat the patient. The minimum software requirements for the treatment planning system are an external beam program, an irregular field routine, and a brachytherapy package.

(i) "Course of treatment" means the planned series of visits that compose a plan for treatment of one or more cancer sites for a single patient.

(j) "Department" means the Michigan Department of Community Health.

(k) "Department Inventory of Megavoltage Radiation Therapy Units" means the list maintained by the Department of (i) the licensed MRT units operating pursuant to a valid certificate of need issued under Part 222 or former Part 221; (ii) licensed, operating MRT units for which the operation of the unit did not require a certificate of need; and (iii) the MRT units that are not yet operational but have a valid certificate of need issued under Part 222 or former Part 221. The list will not include those units approved pursuant to Section 8 of these standards. The list will identify non-special and special purpose MRT units separately.

(l) "Dosimetrist" means a person who is familiar with the physical and geometric characteristics of the radiation equipment and radioactive sources commonly employed and who has the training and expertise necessary to measure and generate radiation dose distributions and calculations under the direction of a medical physicist and/or a radiation oncologist.

(m) “Driving miles” means the number of miles from the city in which the proposed MRT unit will be

located to the closest city in which an existing MRT unit is located. Driving miles is the number of miles from center-of-city to center-of-city shown on the Michigan Department of Transportation map.

(n) "Duplication factor" means the number derived by subtracting the duplication rate from 1.

(o) "Duplication rate" means the percent of new cancer cases in each planning area determined by the Office of the State Registrar and Center for Health Statistics that have been reported more than one time to the Michigan Cancer Surveillance Program.

(p) "Equivalent treatment visit" or "ETV" means a unit of measure, based on the type of treatment visit, that reflects the relative average length of time one patient spends in one treatment visit in an MRT unit. Section 12 sets forth how ETVs shall be calculated.

(q) "Existing megavoltage radiation therapy service" means the facility and equipment at one geographic location used to provide MRT services including but not limited to the simulator(s), block fabrication materials, and all MRT units that are listed on the Department Inventory of MRT Units.

(r) "Expand an existing MRT service" means increasing the number of MRT units (second, third, etc.) at the same geographic location of an existing MRT service.

(s) "F.T.E." or "Full time equivalent" means an individual(s) with normally scheduled working hours of 40 hours per week.

(t) "Gamma knife" means a special stereotactic radiosurgery unit consisting of multiple cobalt sources all simultaneously focused to irradiate cancer or other neoplasms in the brain or cerebrovascular system abnormalities.

(u) "Geographic location" means either (i) the geographic location of a licensed health facility as defined in the Certificate of Need Review Standards applicable to the type of health facility or (ii) if the location is not a health facility as defined in Part 222 of the Code, a distinct geographic location separate from another location.

(v) "Heavy particle accelerator" means a machine such as a cyclotron which produces beams of high energy particles such as protons, neutrons, pions, or heavy ions with masses greater than that of an electron.

(w) "Immediately available" means continuous availability of direct communication with the MRT unit in person or by radio, telephone, or telecommunication.

(x) "Intermediate treatment visit" means a treatment visit involving two separate treatment sites, three or more fields to a single treatment site, or the use of special blocking.

(y) "Intraoperative treatment visit" means a treatment visit where a dose of megavoltage radiation is delivered to a surgically exposed neoplasm or cancerous organ/site.

(z) "IRB" or "institutional review board" means an institutional review board, as defined by Public Law 93-348, that is regulated by Title 45 CFR 46.

(aa) "Licensed hospital site" means either: (i) in the case of a single site hospital, the location of the hospital authorized by license and listed on that licensee's certificate of licensure or (ii) in the case of a hospital with multiple sites, the location of each separate and distinct inpatient site as authorized by licensure.

(bb) "Licensed MRT unit" means an MRT unit that is licensed by the Nuclear Regulatory Commission (NRC) or the Michigan Department of Consumer & Industry Services, Division of Health Facilities and Services, Radiation Safety Section.

(cc) "Medical radiation physicist" means an individual who is (i) board certified or board qualified by the American Board of Radiology in radiological physics or therapeutic radiological physics or (ii) board certified or board qualified by the American Board of Medical Physics in medical physics with special competence in radiation oncology physics.

(dd) "Megavoltage radiation therapy" or "MRT" means a clinical modality in which patients with cancer, other neoplasms, or cerebrovascular system abnormalities are treated with radiation which is delivered by a megavoltage radiation therapy unit.

(ee) "Megavoltage radiation therapy program" means one or more MRT services operated at one or more geographic locations under the same administrative unit.

(ff) "Megavoltage radiation therapy service" means providing megavoltage radiation therapy and/or the utilization of a megavoltage radiation therapy unit(s) at one geographic location.

(gg) "Megavoltage radiation therapy unit" or "MRT unit" or "unit" means a linear accelerator; cobalt unit;

or other piece of medical equipment operating at an energy level equal to or greater than 1.0 million electron volts (megavolts or MEV) for the purpose of delivering doses of radiation to patients with cancer, other neoplasms, or cerebrovascular system abnormalities.

(hh) "Michigan Cancer Surveillance Program" means the program for the collection and analysis of information on cancer in Michigan operated by the Michigan Department of Community Health, Division of the Registrar and Health Statistics, mandated by Act 82 of 1984, being Section 333.2619 of the Michigan Compiled Laws.

(ii) "Multi-disciplinary cancer committee" means a standing committee that (i) includes representatives from the medical specialties or sub-specialties which refer patients to the MRT service; representatives from the specialties of diagnostic radiology, radiation oncology, and pathology; representatives from those who oversee the tumor registry; and representatives from administration, nursing, social services, pharmacy, and rehabilitation; (ii) meets at least on a quarterly basis; and (iii) is responsible for (a) establishing educational and problem oriented multi-disciplinary, facility-wide cancer conferences that include the major anatomic locations of cancer seen at the facility; (b) monitoring, evaluating, and reporting to the medical staff and governing body on the quality of care provided to patients with cancer; and (c) oversight of the applicant's tumor registry for quality control, staging, and abstracting.

(jj) "New cancer case," for purposes of these standards, means a person with any newly diagnosed cancer excluding basal, epithelial, papillary, and squamous cell carcinomas of the skin from other than a genital area.

(kk) "Non-special megavoltage radiation therapy unit" or "non-special MRT unit" or "non-special unit" means an MRT unit other than an MRT unit meeting the definition of a special purpose megavoltage radiation therapy unit.

(ll) "Operating room based intraoperative MRT unit" or "OR-based IORT unit" means an MRT unit that is designed to emit only electrons, is located in an operating room in the surgical department of a licensed hospital, and is available for the treatment of a patient undergoing a surgical procedure with megavoltage radiation.

(mm) "Patient care evaluation studies" means a system of patient care evaluation, conducted at least twice annually, that documents the methods used to identify problems and the opportunities to improve patient care. Examples of patient care evaluation studies include nationwide patient care evaluation studies; hospital wide quality assurance activities; and ongoing monitoring, evaluating, and action planning.

(nn) "Planning area" means the groups of counties shown in Section 16.

(oo) "Relocation of an existing MRT service/unit" means a change in the geographic location within the same planning area of an MRT unit listed on the Department Inventory of MRT Units.

(pp) "Replace/upgrade a megavoltage radiation therapy unit" means an equipment change proposed by an applicant that results in the applicant operating the same number of non-special and the same number and type of special purpose megavoltage radiation therapy units before and after the equipment change.

(qq) "Rural county" means a county not located in a metropolitan area as that term is defined pursuant to the "revised standards for defining metropolitan areas in the 1990's" by the statistical policy office of the office of information and regulatory affairs of the united states office of management and budget, 55 F.R., p.12154 (March 30, 1990).

(rr) "Simple treatment visit" means a treatment visit involving a single treatment site, single treatment field, or parallel opposed fields with the use of no more than simple blocks.

(ss) "Simulation" means the precise mock-up of a patient treatment with an apparatus that uses a diagnostic x-ray tube and duplicates an MRT unit in terms of its geometrical, mechanical, and optical properties.

(tt) "Special purpose megavoltage radiation therapy unit" or "special purpose MRT unit" or "special purpose unit" or "special unit" means any of the following types of MRT units: (i) heavy particle accelerator, (ii) gamma knife, (iii) dedicated stereotactic radiosurgery unit, (iv) dedicated total body irradiator (TBI), or (v) an OR-based IORT unit.

(uu) "Stereotactic treatment visit" means a visit involving the use of a stereotactic guiding device with

radiotherapy for the destruction of a precisely defined intracranial tumor or lesion.

(vv) "Total body irradiator" or "TBI" means a specially modified dedicated cobalt unit certified as a total body irradiator by the Nuclear Regulatory Commission (NRC) or a permanently modified dedicated linear accelerator that uses a very wide beam of gamma rays or x-rays to irradiate the entire body simultaneously.

(ww) "Treatment site" means the anatomical location of the MRT treatment.

(xx) "Treatment visit" means one patient encounter during which megavoltage radiation therapy is administered. One treatment visit may involve one or more treatment ports or fields. Each separate encounter by the same patient at different times of the same day shall be counted as a separate treatment visit.

(yy) "Tumor registry," for the purposes of these standards, means a manual or computerized data base containing information about all malignancies and only those that are diagnosed and/or treated at the applicant's facility. The malignancies must be reportable to the Michigan Cancer Surveillance Program As required pursuant to Public Act 82 of 1984, as amended.

(zz) "Very complex treatment visit" means those visits listed in Section 12 which involve special techniques in the performance of the MRT.

(2) The definitions in Part 222 shall apply to these standards.

Section 3. Modification of the Appendices

Sec. 3. (1) The Commission may modify the Duplication Rates and the Duplication Factors set forth in Appendix A based on data obtained from the Michigan Cancer Surveillance Program presented to the Commission by the Department.

(2) The Commission may periodically modify the Distribution of MRT Courses by Treatment Visit Category set forth in Appendix B based on data provided by MRT providers as part of a Department survey presented to the Commission by the Department.

(3) The Commission shall establish the effective date of the modifications made pursuant to subsections (1) or (2).

(4) The Department shall modify the Department Inventory of MRT Units set forth in Appendix C based on decisions made on certificates of need and certificate of need applications.

(5) Modifications made by the Commission pursuant to subsections (1) or (2) shall not require ad hoc advisory committee action, a public hearing, or submittal of the standard to the Legislature and the Governor in order to become effective.

Section 4. Department Inventory of Megavoltage Radiation Therapy (MRT) Units

Sec 4. Appendix C sets forth the MRT units included in the Department Inventory of MRT Units as of the effective date of these standards. Modification to Appendix C shall be made by the Department pursuant to Section 3.

Section 5. Requirements for approval - applicants proposing to begin operation of a megavoltage radiation therapy unit

Sec. 5. (1) An applicant proposing to begin operation of a megavoltage radiation therapy unit(s) shall demonstrate that:

(a) a minimum of 8,000 equivalent treatment visits (ETVs) for each proposed unit results from application of the methodology described in Section 11 and

(b) the proposed MRT unit is not a special purpose MRT unit.

(2) An applicant that demonstrates all of the following shall not be required to be in compliance with the requirement in subsection (1):

(a) The site of the proposed MRT unit is located in a rural county.

(b) The site of the proposed MRT unit is a licensed hospital site that has 90 or more licensed hospital beds.

(c) The site of the proposed MRT unit is 60 driving miles or more from the nearest existing megavoltage radiation therapy service.

(d) The proposed MRT unit/service projects a minimum of 5,500 equivalent treatment visits (ETVs) for each proposed unit based on the application of the methodology described in Section 11.

(e) The proposed MRT unit is not a special purpose MRT unit.

Section 6. Requirements for approval - applicants proposing to expand an existing megavoltage radiation therapy service

Sec. 6. (1) An applicant proposing to expand an existing MRT service with an additional non-special MRT unit shall demonstrate that an average of 10,000 ETVs was performed in the most recent 12-month period on each of the applicant's non-special MRT units listed on the Department Inventory of MRT Units at the location where the unit is to be added.

(2) An applicant proposing to expand an existing MRT program with a special purpose MRT unit shall demonstrate each of the following, as applicable:

(a) An average of 8,000 ETVs was performed in the most recent 12-month period on each of the applicant's non-special MRT units listed on the Department Inventory of MRT Units at the location where the special purpose unit is to be located. If the special purpose unit will not be located at the same location as the existing MRT program, compliance with this subsection shall be determined based on the average number of ETVs performed on each of the non-special MRT units listed on the Department Inventory of MRT Units for the existing MRT program being expanded.

(b) An applicant proposing to acquire a dedicated total body irradiator shall have either (i) a valid CON issued under former Part 221 or Part 222 to operate a bone marrow transplantation program or (ii) a written agreement to provide total body irradiation services to a hospital that has a valid CON issued under former Part 221 or Part 222 to operate a bone marrow transplantation program. Documentation of the written agreement shall be included in the application at the time it is submitted to the Department.

(c) An applicant proposing to acquire a heavy particle accelerator shall have available, either on-site or through written agreement(s), 3-dimensional imaging and 3-dimensional treatment planning capabilities. Documentation of the written agreement shall be included in the application at the time it is submitted to the Department.

(d) An applicant proposing to acquire and operate a dedicated stereotactic radiosurgery unit (including a gamma knife) shall demonstrate that (i) the applicant has, at the time the application is filed, a formal relationship with a neurosurgeon(s) trained in stereotactic radiosurgery and (ii) on-site 3-dimensional imaging and 3-dimensional treatment planning capabilities.

(e) An applicant proposing to operate an operating room based intraoperative megavoltage radiation therapy unit shall demonstrate that (i) the hospital at which the OR-based IORT unit will be located meets the CON review standards for surgical facilities if the application involves the replacement of or an increase in the number of operating rooms and (ii) the OR-based IORT unit to be installed is a linear accelerator with only electron beam capabilities.

Section 7. Requirements for approval - applicants proposing to replace/upgrade a megavoltage radiation therapy unit(s)

Sec. 7. An applicant requesting to replace/upgrade a MRT unit(s) shall demonstrate each of the following, as applicable.

(1) An applicant requesting to replace/upgrade an existing non-special MRT unit which is the only unit

at that geographic location, shall demonstrate each of the following:

(a) The unit is listed on the current Department Inventory of MRT Units.

(b) The unit was listed on the Department Inventory of MRT Units as of the effective date of these standards.

(c) The unit performed at least 5,500 ETVs in the most recent 12-month period.

(d) The replacement unit will be located at the same geographic location as the unit to be replaced, unless the applicant demonstrates that the requirements of Section 10 also have been met.

(2) An applicant requesting to replace/upgrade an existing non-special MRT unit at a MRT service which is the only MRT service in the planning area shall demonstrate each of the following:

(a) The unit is listed on the current Department Inventory of MRT Units.

(b) Each unit at the geographic location of the unit to be replaced operated at an average of at least 5,500 ETVs in the most recent 12-month period.

(c) The replacement unit will be located at the same geographic location as the unit to be replaced.

(3) An applicant, other than an applicant meeting all of the applicable requirements of subsection (1) or (2), requesting to replace/upgrade a non-special MRT unit shall demonstrate each of the following:

(a) The unit is listed on the current Department Inventory of MRT Units.

(b) Each non-special unit at the geographic location of the unit to be replaced operated at an average of at least 7,000 ETVs in the most recent 12-month period.

(c) The replacement unit will be located at the same geographic location as the unit to be replaced, unless the applicant demonstrates that the requirements of Section 10 also have been met.

(4) An applicant requesting to replace/upgrade an existing special purpose unit shall demonstrate each of the following, as applicable:

(a) The unit is listed on the current Department Inventory of MRT Units as a special purpose MRT unit.

(b) The special purpose unit to be replaced operated at the following level of utilization during the most recent 12-month period, as applicable:

(i) an average of 7,000 ETVs for each heavy particle accelerator;

(ii) an average of 1,000 ETVs for each OR-based IORT unit, gamma knife, dedicated stereotactic radiosurgery unit, or dedicated total body irradiator.

(c) The replacement special purpose unit will be located at the same geographic location as the special purpose unit to be replaced, unless the applicant demonstrates that the applicable requirements of sections 6 and 10 also have been met.

(d) An applicant proposing to replace a dedicated total body irradiator shall have either (i) a valid CON to operate a bone marrow transplantation program or (ii) a written agreement to provide total body irradiation services to a hospital that has a valid CON issued under former Part 221 or Part 222 to operate a bone marrow transplantation program.

(5) An applicant under this section shall demonstrate that the megavoltage radiation therapy unit proposed to be replaced/upgraded is fully depreciated according to generally accepted accounting principles; that the existing unit clearly poses a threat to the safety of the public; or that the proposed replacement unit offers technological improvements which enhance quality of care, increase efficiency, and/or reduce operating costs and patient charges.

Section 8. Requirements for approval - applicants proposing to use megavoltage radiation therapy units exclusively for research

Sec. 8. (1) An applicant proposing a megavoltage radiation therapy unit to be used exclusively for research shall demonstrate each of the following:

(a) The applicant operates a therapeutic radiation residency program approved by the American Medical Association, the American Osteopathic Association, or an equivalent organization.

(b) The megavoltage radiation therapy unit shall operate under a protocol approved by the applicant's institutional review board.

(c) The applicant agrees to operate the unit in accordance with the terms of approval in Section 15(1)(c)(v), (viii), (xiii), (xiv); 15(2); 15(3); and 15(4).

(2) An applicant meeting the requirements of subsection (1) shall be exempt from meeting the requirements and terms of sections 5; 6; 7; and 15(1)(c)(i), (ii), (iii), (iv), (vi), (vii), (ix), (x), (xi), and (xii) of these standards.

Section 9. Requirements for approval - applicants proposing to acquire an existing MRT service/unit

Sec. 9. An applicant proposing to acquire an existing MRT service/unit shall demonstrate that it meets all of the following:

(1) The project is limited solely to the acquisition of an existing MRT service/unit.

(2) The project will not change the number or type (special, non-special) of MRT units listed on the Department Inventory of MRT Units at the geographic location of the MRT service being acquired unless the applicant demonstrates that the project is in compliance with the requirements of Section 5 or 6, as applicable.

(3) The project will not result in the replacement/upgrade of the MRT unit(s) to be acquired unless the applicant demonstrates that the requirements of Section 7 also have been met.

(4) All MRT units at the service to be acquired are currently listed on the Department Inventory of MRT Units.

(5) The applicant agrees to operate the MRT service in accord with all applicable project delivery requirements set forth in Section 15 of these standards.

Section 10. Requirements for approval - applicants proposing to relocate an existing MRT service/unit

Sec. 10. An applicant proposing to relocate an existing MRT service/unit shall demonstrate that it meets all of the following:

(1) The MRT unit(s) to be relocated is listed on the Department Inventory of MRT Units.

(2) The relocation of the MRT unit will not change the number or type (special, non-special) of MRT units in the planning area.

(3) The new geographic location will be in the same planning area as the existing geographic location.

(4) The project will not result in the replacement/upgrade of the MRT unit(s) to be relocated unless the applicant demonstrates that the requirements of Section 7, as applicable, also have been met.

(5) The unit to be relocated is not a special purpose unit unless the location to which the special purpose unit is to be relocated meets the requirements of Section 6, as applicable.

(6) The applicant agrees to all applicable project delivery requirements set forth in Section 15 of these standards.

Section 11. Methodology for computing the projected number of equivalent treatment visits

Sec. 11. The applicant being reviewed under Section 5 shall apply the methodology set forth in this section in computing the projected number of equivalent treatment visits (ETVs).

(1) Identify the number of new cancer cases documented in accord with the requirements of Section 14.

(2) Multiply the number of new cancer cases identified in subsection (1) by the duplication factor identified in Appendix A, for the planning area in which the proposed unit will be located.

(3) Multiply the number of new cancer cases produced in subsection (2) by 0.55 to determine the estimated number of courses of MRT.

(4) Multiply the estimated number of courses of MRT by 20 to determine the total estimated number of treatment visits.

(5) Determine the number of estimated simple, intermediate, and complex treatment visits by multiplying the total estimated number of treatment visits produced in subsection (4) by the percent allocations for each category as set forth in Appendix B.

(6) Multiply the estimated number of treatment visits in the simple category produced in subsection (5) by 1.0.

(7) Multiply the estimated number of treatment visits in the intermediate category produced in subsection (5) by 1.1.

(8) Multiply the estimated number of treatment visits in the complex category produced in subsection (5) by 1.25.

(9) Sum the numbers produced in subsections (6) through (8) to determine the total number of estimated ETVs.

Section 12. Equivalent treatment visits

Sec. 12. For purposes of these standards, equivalent treatment visits shall be calculated as follows:

(1) For the time period specified in the applicable section(s) of these standards, assign each actual treatment visit provided to one applicable treatment visit category set forth in Table 1.

(2) The number of treatment visits for each category in the time period specified in the applicable section(s) of these standards shall be multiplied by the corresponding ETV weight in Table 1 to determine the number of equivalent treatment visits for that category for that time period.

(3) To determine the ETV for intraoperative treatment visits, whether performed on a MRT unit in the radiation oncology department or an OR-based IORT unit, divide the actual, documented number of minutes required to perform each intraoperative treatment visit by 15. The product of this division, rounded up to the next whole number, is the ETV for intraoperative treatment visits. Documentation shall be submitted as part of the CON application and/or on a Department form developed for reporting MRT equivalent treatment visits. If a facility performs intraoperative treatment visits on both a unit located in the radiation oncology department and an OR-based IORT unit, the facility shall maintain separate records for the utilization of each separate unit.

(4) The number of ETVs for each category determined pursuant to subsections (2) and (3) shall be summed to determine the total ETVs for the time period specified in the applicable section(s) of these standards.

TABLE 1

Treatment Visit Category	Equivalent Treatment Visit Weight
Simple	1.00
Intermediate	1.10
Complex	1.25
Very Complex:	
Total Body Irradiation	5.00
Hemi Body Irradiation	4.00
Patient under 5 years of age	2.00
Heavy Particle Accelerator	5.00
Stereotactic radio-surgery (non-gamma knife)	12.00
Gamma Knife	8.00 plus 4 additional ETVs for each iso-center after the first.

Section 13. Commitment of new cancer cases

Sec. 13. (1) An applicant proposing to use new cancer cases shall demonstrate all of the following:

(a)Each entity contributing new cancer case data provides, as part of the application at the time it is submitted to the Department, a signed governing body resolution that states that the number of new cancer cases committed to the application shall not be used in support of any other application for an MRT unit(s) for the duration of the MRT service for which the data are being committed.

(b)The geographic locations of all entities contributing new cancer case data are in the same planning area as the proposed MRT unit(s).

(c)Any entity contributing new cancer case data is not listed on the Department Inventory of MRT Units.

(2)An entity currently operating or approved to operate a unit listed on the Department Inventory of MRT Units shall not contribute new cancer cases to support any MRT unit/service.

Section 14. Documentation of new cancer case data

Sec. 14. (1) An applicant required to document volumes of new cancer cases shall submit, as part of its application, documentation from the Office of the State Registrar verifying the number of new cancer cases provided in support of the application for the most recent calendar year for which verifiable data is available from the State Registrar.

(2) New cancer case data supporting an application under these standards shall be submitted to the Office of the State Registrar using a format and media specified in instructions from the State Registrar.

Section 15. Project delivery requirements - terms of approval for all applicants

Sec. 15. (1) An applicant shall agree that, if approved, megavoltage radiation therapy services shall be delivered in compliance with the following applicable terms of certificate of need approval:

(a) Compliance with these standards.

(b) Compliance with applicable safety and operating standards.

(c) Compliance with the following quality assurance standards:

(i)(A)The non-special megavoltage radiation therapy units and heavy particle accelerators approved pursuant to these standards shall be operating at a minimum average volume of 8,000 ETVs per unit annually by the end of the third full year of operation, and annually thereafter. The following types of special purpose MRT units: OR-based IORT unit, gamma knife, dedicated stereotactic radiosurgery unit and dedicated total body irradiator approved pursuant to these standards shall be operating at a minimum average volume of 1,000 ETVs per special purpose unit annually by the end of the third full year of operation, and annually thereafter. In meeting this requirement the applicant shall not include any treatment visits conducted by megavoltage radiation therapy units approved exclusively for research pursuant to Section 8.

(B) The non-special megavoltage radiation therapy units and heavy particle accelerators approved pursuant to Section (5)(2) of these standards shall be operating at a minimum average volume of 5,500 ETVs per unit annually by the end of the third full year of operation, and annually thereafter. In meeting this requirement, the applicant shall not include any treatment visits conducted by megavoltage radiation therapy units approved exclusively for research pursuant to Section 8.

(ii) An applicant shall establish a mechanism to assure that (a) the megavoltage radiation therapy service is staffed so that the megavoltage radiation therapy unit is operated by physicians and/or radiation therapy technologists qualified by training and experience to operate the unit safely and effectively. For purposes of evaluating this subsection, the Department shall consider it prima facie evidence of a satisfactory quality assurance mechanism as to the operation of the unit if the applicant requires the equipment to be operated by a physician who is board certified or board qualified in either radiation oncology or therapeutic radiology, and/or a radiation therapy technologist certified by the American Registry of Radiological Technologists (ARRT) or the American Registry of Clinical Radiography Technologists (ARCRT). However, the applicant may submit and the department may accept other evidence that the applicant has established and operates a satisfactory quality assurance mechanism to assure that the megavoltage radiation therapy unit is appropriately staffed, and (b) for the MRT service/program operating a dedicated stereotactic radiosurgery unit or a gamma knife, a neurosurgeon(s) trained in each type of special MRT unit being operated is on the active medical staff of the applicant organization.

(iii) At a minimum, the following staff shall be provided: (a) 1 F.T.E. physician trained in radiation oncology for each 250 patients treated with megavoltage radiation therapy annually, (b) 1 radiation physicist immediately available during hours of operation, (c) 1 dosimetrist or physics assistant for every 300 patients treated with megavoltage radiation therapy annually, (d) 2 F.T.E. radiation therapy technologists for every MRT unit per shift of operation (not including supervisory time), and (e) 1 F.T.E. program director who is a physician trained in radiation oncology who may also be the physician required under subsection (iii)(a). For purposes of evaluating this subsection, the department shall consider it prima facie evidence as to the training of the physician(s) if the physician is board certified or board qualified in radiation oncology and/or therapeutic radiology.

(iv) All megavoltage radiation therapy treatments shall be performed under the supervision of a radiation oncologist and at least one radiation oncologist will be on site at the geographic location of the unit during the operation of the unit(s).

(v) The applicant shall have equipment and supplies within the megavoltage therapy unit/facility to handle clinical emergencies that might occur in the unit. Megavoltage radiation therapy facility staff will be trained in CPR and other appropriate emergency interventions and shall be on-site in the megavoltage radiation therapy unit at all times when patients are treated. A physician shall be on-site in or immediately available to the megavoltage radiation therapy unit at all times when patients are treated.

(vi) An applicant shall operate a cancer treatment program. For purposes of evaluating this

subsection, the department shall consider it prima facie evidence of meeting this requirement if the applicant submits evidence of a cancer treatment program approved by the American College of Surgeons Commission on Cancer. However, the applicant may submit and the Department may accept other evidence that the applicant operates a cancer treatment program as defined in these standards.

(vii) A megavoltage radiation therapy service will have simulation capability at the same geographic location of the megavoltage radiation therapy service/unit.

(viii) An applicant shall participate in the Michigan Cancer Surveillance Program.

(ix) An applicant required to document new cancer cases shall agree to pay the State Registrar's costs for verification of the new cancer case data.

(x) The applicant shall accept referrals for megavoltage radiation therapy services from all appropriately licensed health care practitioners.

(xi) The applicant, to assure that the megavoltage radiation therapy unit will be utilized by all segments of the Michigan population, shall: (a) not deny megavoltage radiation therapy services to any individual based on ability to pay or source of payment, (b) provide megavoltage radiation therapy services to an individual based on the clinical indications of need for the service, and (c) maintain information by payor and non-paying sources to indicate the volume of care from each source provided annually. Compliance with selective contracting requirements shall not be construed as a violation of this term.

(xii)(A) The applicant shall participate in a data collection network established and administered by the department. The data may include but is not limited to annual budget and cost information, operating schedules, through-put schedules, demographic and diagnostic information, and the volume of care provided to patients from all payor sources and other data requested by the Department, and approved by the Certificate of Need Commission. The applicant shall provide the required data on a separate basis for each separate and distinct geographic location or unit, and separately for non-special MRT units and each type of special purpose MRT unit, as required by the Department; in a format established by the Department; and in a mutually agreed upon media. The Department may elect to verify the data through on-site review of appropriate records.

(B) If the applicant intends to include research treatment visits conducted by a megavoltage radiation therapy unit other than an MRT unit approved exclusively for research pursuant to Section 8 in its utilization statistics, the applicant shall submit to the department a copy of the research protocol with evidence of approval by the institutional review board. The applicant shall submit this at the time the applicant intends to include research procedures in its utilization statistics. The applicant shall not report to the Department any treatment visits conducted by an MRT unit approved pursuant to Section 8.

(xiii) Equipment that is replaced shall be removed from service.

(xiv) The applicant shall notify the Department in writing within 10 days of the date when any MRT unit(s) begins operation.

(xv) The applicant agrees to operate a special purpose MRT unit(s) only for the specific use for which it was approved and to seek approval under a separate CON application to operate the unit as a non-special MRT unit.

(xvi) An applicant approved to operate a dedicated total body irradiator that uses cobalt as the source of radiation shall obtain and maintain Nuclear Regulatory Commission certification as a total body irradiator. An applicant approved to operate a dedicated total body irradiator that is a permanently modified linear accelerator shall meet any requirements specified by the Department of Consumer & Industry Services, Division of Health Facilities and Services, Radiation Safety Section.

(2) An applicant for a megavoltage radiation therapy unit under Section 8 shall agree that the services provided by the megavoltage radiation therapy unit approved pursuant to Section 8 shall be delivered in compliance with the following terms of certificate of need approval:

(a) The capital and operating costs relating to the research use of the megavoltage radiation therapy unit approved pursuant to Section 8 shall be charged only to a specific research account(s) and not to any patient or third-party payor.

(b) The megavoltage radiation therapy unit approved pursuant to Section 8 shall not be used for any purposes other than as approved by the institutional review board unless the applicant has obtained certificate of need approval for the megavoltage radiation therapy unit pursuant to Part 222 and these

standards, other than Section 8.

(3) The operation of and referral of patients to the megavoltage radiation therapy unit shall be in conformance with 1978 PA 368, Sec. 16221, as amended by 1986 PA 319; MCL 333.16221; MSA 14.15 (16221).

(4) The applicable agreements and assurances required by this section shall be in the form of a certification authorized by the owner or governing body of the applicant or its authorized agent.

Section 16. Planning areas

Sec. 16. Counties assigned to each planning area are as follows:

PLANNING AREA	COUNTIES		
1	Livingston	Monroe	St. Clair
	Macomb	Oakland	Washtenaw
	Wayne		
2	Clinton	Hillsdale	Jackson
	Eaton	Ingham	Lenawee
3	Barry	Calhoun	St. Joseph
	Berrien	Cass	Van Buren
	Branch	Kalamazoo	
4	Allegan	Mason	Newaygo
	Ionia	Mecosta	Oceana
	Kent	Montcalm	Osceola
	Lake	Muskegon	Ottawa
5	Genesee	Lapeer	Shiawassee
6	Arenac	Huron	Roscommon
	Bay	Iosco	Saginaw
	Clare	Isabella	Sanilac
	Gladwin	Midland	Tuscola
	Gratiot	Ogemaw	
7	Alcona	Crawford	Missaukee
	Alpena	Emmet	Montmorency
	Antrim	Gd Traverse	Oscoda
	Benzie	Kalkaska	Otsego
	Charlevoix	Leelanau	Presque Isle
	Cheboygan	Manistee	Wexford
8	Alger	Gogebic	Mackinac
	Baraga	Houghton	Marquette
	Chippewa	Iron	Menominee
	Delta	Keweenaw	Ontonagon
	Dickinson	Luce	Schoolcraft

Section 17. Effect on prior planning policies; comparative reviews

Sec. 17. (1) These certificate of need review standards supersede and replace the Certificate of Need Review Standards for Megavoltage Radiation Therapy Services/Units approved by the Certificate of Need Commission on September 22, 1998 and effective December 10, 1998.

(2) Projects reviewed under these standards shall not be subject to comparative review.

APPENDIX A

DUPLICATION RATES AND FACTORS

PLANNING AREA	DUPLICATION RATE	DUPLICATION FACTOR
1	0.045538	0.9545
2	0.084510	0.9155
3	0.061473	0.9385
4	0.065971	0.9340
5	0.092521	0.9075
6	0.096870	0.9031
7	0.130801	0.8692
8	0.089036	0.9110

APPENDIX B

DISTRIBUTION OF MRT COURSES BY TREATMENT VISIT CATEGORY

Treatment Visit Category	Statewide Percent
Simple	12%
Intermediate	26%
Complex	62%

Source: Special Survey of Megavoltage Radiation Services, Michigan Department of Community Health, June 1991.

APPENDIX C

DEPARTMENT INVENTORY OF MEGAVOLTAGE RADIATION THERAPY UNITS

PLANNING AREA 1	NO. OF NON-SPECIAL MRT UNITS	NO. OF SPECIAL MRT UNITS
North Oakland Medical Center Pontiac	1	
Mercy Hospital Port Huron	1	
St. Joseph Mercy Hospital Ann Arbor	4	
University of Michigan Hospitals Ann Arbor	4	
St. Mary's Hospital Livonia	1	
Oakwood Hospital Dearborn Southgate	 2 1	
William Beaumont Hospital Royal Oak	3	
William Beaumont Hospital Troy	1	
Grace Hospital Division (Outer Drive) Detroit	2	
PHMC Cancer Center Southfield Novi	 1 1	
Sinai Hospital Detroit	2	
St. John Macomb Hospital Warren	2	

PLANNING AREA 1-continued	**NO. OF NON-SPECIAL MRT UNITS**	**NO. OF SPECIAL MRT UNITS**
American Oncologic Associates (MI Institute for Radiation Oncology - MIRO) Pontiac	2	
Downriver Center for Oncology Brownstown Township	1	
Garden City Radiation Therapy Association Garden City	1	
Grosse Pointe Physicians X-Ray Center Grosse Pointe Woods	1	
Harper Hospital Detroit Rochester	4 1	3
Henry Ford Hospital Detroit	3	
Henry Ford Hospital West Bloomfield	1	
Huron Valley Hospital Milford	1	
RADS, PC Monroe Farmington Hills Clarkston Cancer Treatment Ctr.	1 1 1	
Radiation Oncologists Rochester Hills Mt. Clemens	1 1	
St. John Hospital Detroit	2	
St. Joseph Mercy of Macomb Clinton Township	1	
X-Ray Treatment Ctr., P.C. East Detroit St. Clair Shores	1 1	

PLANNING AREA 2	**NO. OF NON-SPECIAL MRT UNITS**	**NO. OF SPECIAL MRT UNITS**
Edward W. Sparrow Hospital Lansing	3	
Emma L. Bixby Hospital Adrian	1	
WA Foote Hospital Jackson	2	
Radiation Oncology Alliance Lansing	1	
PLANNING AREA 3		
Battle Creek Health System Battle Creek	1	
Borgess Medical Center/Bronson Methodist Hospital Kalamazoo (joint)	2	
Mercy Memorial Medical Center St. Joseph	2	
PLANNING AREA 4		
Hackley Hospital Muskegon	2	
Blodgett Memorial Medical Center dba Spectrum Health E. Grand Rapids	1	
Butterworth Hospital dba Spectrum Health Grand Rapids Big Rapids (NW Radiation Oncology Center)	2 1	
Lakeshore Area Rad. Oncology Ctr. Holland	1	
St. Mary's Hospital Grand Rapids	1	

PLANNING AREA 5	**NO. OF NON-SPECIAL MRT UNITS ***	**NO. OF SPECIAL MRT UNITS**
Genesys Health System Grand Blanc	2	
Hurley Medical Center Flint	2	
McLaren General Hospital Flint	2	
PLANNING AREA 6		
Bay Medical Center Bay City	1	
Saginaw (Saginaw Radiation Oncology Center	1	
Mid-Michigan Medical Center Midland	1	
Alma	1	
St. Mary's Medical Center Saginaw	2	1
Central Michigan Comp. Oncology Ctr (West Branch)	1	
PLANNING AREA 7		
Munson Medical Center Traverse City	2	
Northern Michigan Hospital Petoskey	2	
PLANNING AREA 8		
Marquette General Hospital Marquette	2	